

PART III: CONSUMER INFORMATION

◇ Sandoz Methylphenidate Tablets 10 and 20 mg (methylphenidate hydrochloride tablets)

◇ Sandoz Methylphenidate SR Tablets 20 mg (methylphenidate hydrochloride extended-release tablets)

This leaflet is part III of a three-part "Product Monograph" published when Sandoz Methylphenidate was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about Sandoz Methylphenidate. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

This information for patients or their parents or caregivers is about Sandoz Methylphenidate, a medication intended for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) or narcolepsy for adults and children over 6 years of age. It is very important that ADHD be accurately diagnosed and that the need for medication be carefully assessed. It is important to remember that Sandoz Methylphenidate is only part of the overall management of ADHD. Parents, teachers, physicians and other professionals are part of a team that must work together.

What the medication is used for:

Sandoz Methylphenidate belongs to a group of medicines called central nervous system stimulants. It is used for the treatment of ADHD and narcolepsy. Sandoz Methylphenidate tablets contain methylphenidate hydrochloride, the active ingredient in the treatment of ADHD and narcolepsy.

1) When used in ADHD, Sandoz Methylphenidate improves behaviour by reducing restlessness and increasing attention. Sandoz Methylphenidate, however, will not cure ADHD. Treatment with Sandoz Methylphenidate or other stimulants should always be combined with other treatment measures, such as psychological counseling and educational tutoring by skilled and experienced therapists.

Children and/or adolescents treated with Sandoz Methylphenidate do not seem to become addicted or

abuse drugs later in life. However, central nervous stimulants, including Sandoz Methylphenidate, should only be given under close medical supervision to patients whose condition has been properly diagnosed.

About ADHD

Attention Deficit Hyperactivity Disorder (ADHD) is a disorder characterized by symptoms of inattentiveness and/or hyperactivity-impulsivity inappropriate to the patient's age which interfere with functioning in two or more settings (e.g., school and home). Symptoms of inattention may include not paying attention, making careless mistakes, not listening, not finishing tasks, not following directions, and being easily distracted. Symptoms of hyperactivity-impulsiveness may include fidgeting, talking excessively, running around at inappropriate times, and interrupting others. Some patients have more symptoms of hyperactivity and impulsiveness while others have more symptoms of inattentiveness. Some patients have both types of symptoms. Symptoms must be present for at least 6 months to be certain of the diagnosis.

2) When used in narcolepsy, Sandoz Methylphenidate may relieve the inappropriate daytime sleepiness; however, many people suffering from narcolepsy need additional treatment aimed at other aspects of this condition.

About Narcolepsy

Persons who suffer from narcolepsy experience attacks of sleepiness during the day although they may have enough sleep at night. These attacks usually occur in unusual situations such as standing, eating or the middle of a conversation. Some people find their head falling forward, jaw dropping, knees buckling or even falling to the ground while they are conscious. These attacks may be brought on by emotional situations such as hearty laughter, excitement, sadness or anger.

What it does:

ADHD

Sandoz Methylphenidate works by improving the activity of certain parts of the brain which are underactive. Sandoz Methylphenidate improves attention (attention span) and concentration, and reduces impulsive behaviour.

Narcolepsy

Sandoz Methylphenidate relieves excessive daytime sleepiness in patients suffering from narcolepsy.

When it should not be used:

IMPORTANT: PLEASE READ

Sandoz Methylphenidate should not be used if you or your child:

- Have ever had heart problems – such as a heart attack, irregular heartbeat, chest pain (angina), heart failure, heart disease or were born with a heart problem.
- Have moderate to severe high blood pressure (hypertension) or narrowing of the blood vessels (arterial occlusive disease that can cause pain in the arms and legs).
- Have arteriosclerosis (hardened arteries)
- Have any thyroid problems
- Have significant anxiety, tension, or agitation since Sandoz Methylphenidate may make these conditions worse.
- Are allergic to methylphenidate or any of the other ingredients in Sandoz Methylphenidate (see What the non-medicinal ingredients are). If you think you may be allergic, talk to your doctor for advice.
- Have increased eye pressure (glaucoma).
- Have Tourette’s syndrome, including uncontrolled speech (verbal tics) and body movements (motion tics) or a family history of Tourette’s syndrome.
- Are taking a medicine called a monoamine oxidase inhibitor (MAOI) used for depression, or have taken an MAOI in the last 14 days (see INTERACTIONS WITH THIS MEDICATION).
- Have a tumor of the adrenal gland called pheochromocytoma.

What the medicinal ingredient is:

Methylphenidate hydrochloride

What the non-medicinal ingredients are:

Sandoz Methylphenidate:

10 mg tablet: corn starch, FD&C Green No. 3, lactose, magnesium stearate, polyethylene glycol, sugar and talc.

20 mg tablet: D&C Yellow No. 10, lactose, magnesium stearate, polyethylene glycol, sugar, tragacanth and talc.

Sandoz Methylphenidate SR (20 mg) tablet: cellulose compounds, cetostearyl alcohol, castor oil compounds, lactose, magnesium stearate, talc and titanium dioxide

What dosage forms it comes in:

Sandoz Methylphenidate 10 mg tablets are packaged in bottles of 100.

Sandoz Methylphenidate 20 mg tablets are packaged in

bottles of 100.

Sandoz Methylphenidate SR 20 mg tablets are packaged in bottles of 100.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

Drug Abuse and dependence

Abuse of Sandoz Methylphenidate SR can lead to dependence. Tell your doctor if you have ever abused or been dependent on alcohol or drugs, or if you are now abusing or dependent on alcohol or drugs.

The following have been reported with use of Sandoz Methylphenidate and other medicines used to treat ADHD:

1. Heart-related problems:

- **sudden death in patients who have heart problems or heart defects**
- **stroke and heart attack in adults**
- **increased blood pressure and heart rate**

Sudden death has been reported with drugs used for ADHD treatment in children/adolescents with structural heart abnormalities or other serious heart problems. Although some serious heart problems alone can carry an increased risk of sudden death, Sandoz Methylphenidate generally should not be used in children, adolescents or adults with known structural heart abnormalities or other serious heart disease or conditions.

Tell your doctor if you or, your child, have any heart problems, heart defects, high blood pressure, or a family history of these problems.

Your doctor may wish to check you or your child carefully for heart problems before starting Sandoz Methylphenidate.

Your doctor may wish to check your or your child’s blood pressure and heart rate regularly during treatment with Sandoz Methylphenidate.

Call your doctor right away if you or your child has any signs of heart problems such as chest pain, shortness of breath, or fainting while taking Sandoz Methylphenidate.

Tell your doctor immediately if you experience abnormally sustained or frequent and painful erections of the penis on Methylphenidate treatment or after treatment discontinuation. This can occur in any age group and may

need urgent medical treatment.

If you experience a combination of the following symptoms: restlessness, tremor, sudden muscle contractions, abnormal high temperature and nausea and vomiting while taking methylphenidate with medicines that raise the level of serotonin in the body (serotonergic medicines, for example those used to treat depression like sertraline and venlafaxine), stop treatment with methylphenidate and medicines that raise the level of serotonin in the body and **tell your doctor immediately.**

2. Mental (Psychiatric) problems:

- **new or worse thoughts or feelings related to suicide (thinking about or feeling like killing yourself) and suicide actions (including suicide attempt, suicidal ideation and completed suicide)**
- **new or worse bipolar illness, characterized by extreme mood swings, with periods of mania (unusually excited, over-active or un-inhibited alternating with periods of depression (feelings of sadness, worthlessness or hopelessness))**
- **new or worse aggressive behaviour or hostility**
- **new psychotic symptoms (such as hearing voices, believing things that are not true, are suspicious) or new manic symptoms.**

These new or worse mental problems may be more likely to occur if you/your child have mental disorders that you may or may not know about. Tell your doctor about any mental problems or about any personal or family history of suicide, bipolar illness, or depression you or your child have.

A small number of patients taking ADHD drugs may experience unusual feelings of agitation, hostility or anxiety, or have impulsive or disturbing thoughts such as thoughts of suicide, self-harm or harm to others. Those suicidal thoughts or behaviors may occur at any time during treatment, particularly at the start or during dose changes, and also after stopping Sandoz Methylphenidate. **Should this happen to you, or to those in your care if you are a caregiver or guardian, consult your doctor immediately. Close observation by a doctor is necessary in this situation.**

Call your doctor right away if you or your child have any new or worsening mental symptoms or problems while taking Sandoz Methylphenidate, especially seeing or hearing things that are not real, believing things that are not real, or are suspicious.

BEFORE you or your child uses Sandoz Methylphenidate talk to your doctor or pharmacist if you or your child:

- Have structural heart abnormalities.
- Have a family history of sudden death or death related to heart problems.
- Have any other current or previous heart problems.
- Do strenuous exercise.
- Take other stimulant drugs.
- Have a history of drug or alcohol abuse
- Have motion tics or if any other family members suffer from tics. Signs of tics that are hard to control, repeated twitching of any parts of the body or repeating sounds and words.
- Have someone in your family with Tourette's syndrome.
- Have had fits (convulsions, epilepsy, seizures) or abnormal EEGs (electroencephalograms).
- Have mild high blood pressure.
- Have an abnormal heart rate or rhythm.
- Have or have had any disorder of the blood vessels in the brain, e.g., weakening of blood vessels (aneurysm), stroke, inflammation of blood vessels (vasculitis).
- Have aggressive behaviour.
- Have any suicidal thoughts or behavior.
- Have mental problems or family history of mental problems, including psychosis, mania, bipolar illness, depression or suicide.
- Have circulation problems in fingers and toes, including numbness; feeling cold or pain (This is also known as Raynaud's Phenomenon).

Tell your doctor immediately if you develop any of the above conditions or symptoms while taking Sandoz Methylphenidate. The doctor will decide if you can start or continue taking Sandoz Methylphenidate.

Before taking Sandoz Methylphenidate, tell your doctor if you are pregnant or plan for pregnancy (women and men).

If you take Sandoz Methylphenidate, it can be in your breast milk. Do not breast-feed during your treatment with Sandoz Methylphenidate SR. Tell your doctor if you are nursing a baby.

Sandoz Methylphenidate may cause dizziness, drowsiness, blurred vision, hallucination or other central nervous system side effects, which can affect concentration. If you experience such symptoms, do not drive or use machines, or do other activities that need quick reactions until you know how this medication affects you.

Monitoring during treatment with Sandoz Methylphenidate

To see if Sandoz Methylphenidate is having any unwanted effects, the doctor will check from time to time the patient's health conditions (e.g. blood pressure, heart rate) and will also monitor the growth of children taking Sandoz Methylphenidate. Blood tests will be carried out to monitor the amount of blood cells (white blood cells, red blood cells and platelets) if a patient takes Sandoz Methylphenidate for a long time.

Sandoz Methylphenidate should not be used in children under 6 years of age.

INTERACTIONS WITH THIS MEDICATION

Both your doctor and your pharmacist should also be informed of all medicines you are taking, including herbal medicines or drugs are not taken on a regular basis and are available without prescription

Do not take Sandoz Methylphenidate if you are taking

- A medicine called a monoamine oxidase inhibitor (MAOI, used to treat depression), or have taken an MAOI in the last 14 days. Taking a MAOI with Sandoz Methylphenidate may cause a sudden increase in your blood pressure (see When it should not be used).

Sandoz Methylphenidate may change the way your body reacts to certain medicines. It is important that you tell your doctor or pharmacist if you are taking any of these medicines, it may be necessary to change the dose or in some cases to stop one of the medicines. These include:

- medicines that increase blood pressure,
- phenylbutazone (used to treat pain or fever),
- alpha-2 agonists like clonidine (used to treat high blood pressure),
- medicines used to treat depression,
- medicines used to prevent seizures,
- medicines used to prevent blood clots, e.g. coumarin anticoagulants (commonly called "blood thinners"),
- medicines that influence the level of dopamine in the body (dopaminergic medicines used to treat Parkinson's disease or psychosis).
- medicines that raise the level of serotonin in the body (serotonergic medicines, for example those used to treat depression like sertraline and venlafaxine).

Having an Operation

If you are going to have an operation, tell the doctor that

Sandoz Methylphenidate

you are on treatment with Sandoz Methylphenidate. You should not take Sandoz Methylphenidate on the day of your operation if a certain type of anesthetic is used. This is because there is a chance of a sudden rise in blood pressure and heartbeat during the operation.

Taking Sandoz Methylphenidate with food and drink

Do not drink alcohol while taking Sandoz Methylphenidate. Alcohol may make the side effects of Sandoz Methylphenidate worse. Remember that some foods and medicines contain alcohol.

Drug testing

Sandoz Methylphenidate may give a false positive result when testing for drug use. This includes testing used in sport.

PROPER USE OF THIS MEDICATION

Usual dose:

Sandoz Methylphenidate comes in tablets to be taken by mouth. The doctor determines how much and how often you should take Sandoz Methylphenidate according your individual needs. In order for you to receive the most benefits from Sandoz Methylphenidate, it is important that Sandoz Methylphenidate be taken only as directed by the doctor. Take only the amount of medication at the time intervals and for the time period that the doctor has prescribed.

Children should not take more than 60 mg of Sandoz Methylphenidate per day.

If Sandoz Methylphenidate SR (extended-release) tablets have been prescribed, these tablets must be swallowed whole and never be crushed or chewed.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

The symptoms of overdose are: vomiting, agitation, headache, tremors, muscle twitching, irregular heart beat, flushing, fever, sweating, dilated pupils, breathing difficulties, confusion, and fits; muscle spasms, fever, red-brown coloured urine which could be possible signs of abnormal breakdown of muscles (rhabdomyolysis).

Missed Dose:

If a dose of Sandoz Methylphenidate is missed, you should take it as soon as possible. The remaining doses for that day should be taken at regularly spaced intervals. Do not take a double dose of Sandoz Methylphenidate to make up the missed dose. If you have any questions about this, check with the doctor.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, Sandoz Methylphenidate can have some side effects, although not everybody gets them. These are usually mild to moderate and generally do not last long.

Taking Sandoz Methylphenidate with food may reduce stomach discomfort.

Sandoz Methylphenidate may cause sleeplessness if taken too close to bedtime.

Slower growth (weight gain and/or height) has been reported with long-term use of methylphenidate in children. Your doctor will be carefully watching your height and weight. If you are not growing or gaining weight as your doctor expects, your doctor may stop your Sandoz Methylphenidate treatment.

Some side effects are very common:

These side effects may affect more than 1 in 10 patients.

- sore throat and runny nose
- decreased appetite
- nervousness
- difficulty in falling asleep
- nausea, dry mouth

Some side effects are common:

These side effects may affect between 1 and 10 in every 100 patients.

- excessive emotional distress, troubled, sleep disturbance, emotional excitement, restlessness
- trembling, headache, dizziness, sleepiness
- changes in blood pressure (usually an increase), abnormal heart rhythm, palpitation
- cough
- vomiting, stomach pain, upset stomach, indigestion, toothache
- skin rash, itchy rash and hives (urticaria), fever, hair loss
- excessive sweating
- joint pain
- decreased weight
- feeling jittery

Some side effects are rare:

These side effects may affect between 1 and 10 in every 10,000 patients.

- slowing of growth (height and weight) during prolonged use in children
- blurred vision, trouble seeing

Some side effects are very rare:

These side effects may affect less than 1 in every 10,000 patients.

- low red blood cell count (anemia), low platelet count (thrombocytopenia), low white blood cell count (leucopenia)
- unusually active, depressed mood
- uncontrolled speech and body movements (Tourette's syndrome)
- abnormal liver function including liver coma
- muscle cramps

Some other side effects (Frequency: Not Known):

- abnormal liver function including liver coma
- irritated, aggression, mood changes, abnormal behaviour or thinking, anger, excessive awareness of surroundings, feeling unusually excited, over-active and un-inhibited (mania), feeling disorientated, changes in sex drive, lack of feeling or emotion, doing things over and over again, being obsessed with one thing, confusion, addiction
- temporary muscle weakness, loss of skin sensation or other functions of the body due to a temporary lack of blood supply to the brain (reversible ischaemic neurological deficit), migraine
- double vision, dilated pupils
- stopped heartbeat, heart attack
- shortness of breath
- diarrhea, constipation
- swelling of face and throat, redness of the skin, large red blotches on the skin appearing within a few hours of taking the medicine
- muscle pain
- blood in the urine
- swelling of the breasts in men
- tiredness
- abnormal sounds from heart

Other side effects not listed above may occur in some patients. If you notice any other effects, tell your doctor immediately.

This is not a complete list of possible side effects. Ask your doctor about other side effects. If any side effects develop,

talk to your doctor.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist		Seek immediate medical help
		Only if severe	In all cases	
Common	Fast heartbeat, chest pain			√
	Dyskinesia: uncontrollable twitching and jerking			√
Very Rare	Severe allergic reactions: swelling of lips or tongue, or difficulty in breathing			√
	Signs of stroke: severe headache or confusion, weakness or paralysis of limbs or face, difficulty speaking			√
	Neuroleptic Malignant Syndrome: sudden high fever, very high blood pressure and severe convulsions			√
	Thrombocytopenic purpura: bleeding under the skin, bruising		√	
	Muscle twitching or tics	√		
	Low white blood cell count: sore throat and fever or chills	√		
	Choreoathetoid movements: uncontrollable writhing		√	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect	Talk with your doctor or pharmacist		Seek immediate medical help	
	Only if severe	In all cases		
movements of the limb, face and/or trunk				
Hallucinations: seeing or feeling things that are not really there			√	
Seizures: fits convulsions, epilepsy			√	
Exfoliative dermatitis: skin blisters or itching			√	
Erythema multiforme: red blotches on the skin		√		
Unknown	New Psychotic or Manic Symptoms: -Paranoia, delusions -Hallucinations: seeing, feeling or hearing things that are not real -Mania: feeling unusually excited, over-active, or uninhibited		√	
	Aggressive Behaviour or Hostility		√	
	Suicidal Behaviour: Thoughts or actions about suicide or hurting yourself			√
	Long-lasting (greater than 4 hours in duration) and painful erection of the			√

IMPORTANT: PLEASE READ

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Seek immediate medical help
	Only if severe	In all cases	
penis			
Unknown	Raynaud's Phenomenon: discoloration of the fingers and toes, pain, sensations of cold and/or numbness		√

This is not a complete list of side effects. For any unexpected effects while taking Sandoz Methylphenidate contact your doctor or pharmacist.

HOW TO STORE IT

Protect Sandoz Methylphenidate from moisture and heat. Store between 2 and 30°C.

Sandoz Methylphenidate tablets should not be used after the expiry date shown on the package label. Remember to take back unused medicine to your pharmacist.

Keep out of reach and sight of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to:

Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

Please consult your doctor or pharmacist with any questions or concerns you may have regarding your individual condition.

This document plus the full product monograph, prepared for health professionals can be found at: <http://www.sandoz.ca>

or by contacting the sponsor, Sandoz Canada Inc., at: 1-800-361-3062

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